

PHARMACY HAZARDOUS WASTE DISPOSAL

ARE YOU AWARE THAT THE PHARMACY YOU WORK IN GENERATES HAZARDOUS WASTE, AND IF THIS WASTE IS NOT PROPERLY DISPOSED OF, THE PHARMACY CAN BE **FINED** BY THE EPA? THE EPA HAS ALREADY FINED PHARMACIES ACROSS THE UNITED STATES AND IN KENTUCKY FOR THIS VIOLATION.

BACKGROUND: Both federal and state regulations require pharmacy hazardous waste to be properly handled. Pharmacy stock bottles identified as "P-Rated", e.g., Coumadin, and certain expired product, expired returned to stock product, customer returns, dropped or loose pills and compounding chemicals are to be handled as pharmacy hazardous waste to comply with federal and state regulations. Similar to other universal wastes, pharmaceutical wastes are produced by a large and diverse community of generators, often in small volumes. For example, it has been estimated that LQG hospitals in the United States generate a total of 10,600 tons of RCRA hazardous pharmaceuticals waste annually, while a single retail pharmacy may only generate 5 pounds of hazardous pharmaceutical wastes in a year ("Assessment of the Potential Costs, Benefits, and Other Impacts of Adding Pharmaceuticals to the Universal Waste Rule, as Proposed." October 2008). Within these facilities, hazardous pharmaceutical waste may be generated in a single location (such as a pharmacy), or in multiple locations (such as hospital pharmacies, emergency rooms, operating rooms, and nursing stations) by many individuals. Pharmaceutical wastes may be RCRA hazardous because they contain any of 31 listed hazardous waste chemicals, although many may be identified by a commercial name (rather than a chemical name), making it more difficult to readily identify them as hazardous, has made implementation of the RCRA hazardous waste regulations difficult for many of these facilities. The universal waste regulations help avoid such mismanagement by streamlining the collection requirements for certain hazardous wastes.

WARNING: Do not discard these items in normal trash. Pharmaceutical wastes that are hazardous wastes must be handled by an individual who is an approved environmental waste transporter in terms of removing or transporting hazardous waste out of your store.

WHOSE RESPONSIBILITY IS IT TO DETERMINE IF WASTE IS HAZARDOUS?: Hazardous wastes are those substances, which are being discarded and meet the regulatory definition of a hazardous waste based on toxicity, ignitability, corrosivity or reactivity. It is the responsibility of the **pharmacy** to determine if their wastes are hazardous. ("Acute hazardous waste" → all "P" listed wastes). The waste determination is the principal component of the hazardous waste regulations. As the generator, the **pharmacy** may make the waste determination by knowledge or testing and is required to maintain records documenting their determination. Waste may be classified as hazardous due to its listing or by characteristic. Below are the hazardous waste categories and the corresponding regulation that will help you make a determination.

Hazardous Waste Type	Regulation
Ignitable characteristic waste	40 CFR 261.21
Corrosive characteristic waste	40 CFR 261.22
Reactive characteristic waste	40 CFR 261.23
Toxic characteristic waste	40 CFR 261.24
F-listed waste	40 CFR 261.31
K-listed waste	40 CFR 261.32
P-listed waste	40 CFR 261.33 (e)
U-listed waste	40 CFR 261.33 (f)

The most commonly P & U-listed wastes with waste codes that are found in **Pharmacies** are:

<u>Name</u>	<u>Hazardous Waste Number</u>	<u>Name</u>	<u>Hazardous Waste Number</u>
Arsenic trioxide	P012	Hexachlorophene	U132
Epinephrine	P042	Lindane	U129
Nicotine	P075	Melphalan (chemo)	U150
Nitroglycerin ¹	P081	Mercury	U151
Physostigmine	P204	Mitomycin C (chemo)	U010
Physostigmine salicylate	P188	Paraldehyde (CIV)	U182
Warfarin >0.3%	P001	Phenacetin	U187
Chloral Hydrate (CIV) ²	U034	Phenol	U188
Chlorambucil (chemo)	U035	Reserpine	U200
Chloroform	U044	Resorcinol	U201
Cyclophosphamide (chemo)	U058	Saccharin	U202
Daunomycin (chemo)	U059	Selenium sulfide	U205
Dichlorodifluoromethane	U075	Streptozotocin (chemo)	U206
Diethylstilbestrol	U089	Trichloromonofluoromethane	U121
Formaldehyde	U122	Uracil mustard (chemo)	U237
		Warfarin <0.3%	U248

HOW DO I DETERMINE MY GENERATOR STATUS AND WHAT AM I REQUIRED TO DO?: The term “generator” applies to any individual or business (**pharmacy**) that creates hazardous waste. See 401 KAR 30:010 for the definition of a generator.

There are three categories of generators with each having its own set of requirements:

1) Conditionally Exempt Small Quantity Generator (CESQG):

- Generates <1kg (2.2 pounds) of acute hazardous waste or <100 kg of non-acute hazardous waste in a calendar month
 - ✓ Not required to register or have an EPA ID number

- ✓ Exempt from registration fee

2) Small Quantity Generator (SQG):

- Generates 100kg but <1000 kg of non-acute hazardous waste in a calendar month
- Will automatically be a LQG if >1 kg (2.2 pounds) of acute hazardous waste is generated in a calendar month
 - ✓ Required to register or have an EPA ID number
 - ✓ Registration fee required

3) Large Quantity Generator (LQG):

- Generates >1kg (2.2 pounds) of acute hazardous waste in a calendar month
- Generates more than 1000 kg of non-acute hazardous waste in a calendar month
 - ✓ Required to register or have an EPA ID number
 - ✓ Registration fee required

HOW DO I REGISTER AS A HAZARDOUS WASTE GENERATOR?:

Registration:

Pharmacies are required to notify the Kentucky Department of Environmental Protection, Division of Waste Management (hereafter Division) of all hazardous waste activity.

- SGQs and LQGs must register with the Division and obtain an EPA ID number.
 - **Pharmacies** must complete a "Registration of Hazardous Waste Activity" form (DEP-7037) which can be obtained by telephone, fax, e-mail or located on the Division's internet page
- Upon completion of the registration form, a "Certificate of Registration" will be issued that contains:
 - EPA ID number, that is:
 - Site-specific and cannot be transferred
 - Required for each location unless the sites are "contiguous," meaning there are no public streets separating the properties.
 - Waste streams you are registering as hazardous
 - Expiration date (note: registration must renew annually)

Fees:

- Initial registration fee = \$300

Modification to the Certificate Registration:

- Modifications:
 - Adding/Deleting Waste stream
 - Changing the contact person/ mailing address
 - Changing generator status
- Modification to the registration must be filed within 30 days of the date of the change using the Division Form #DEP-7037.
- Company name change = only change not subject to the modification fee

HOW DO I DETERMINE THE ACCUMULATION TIME LIMITS?: It is a serious violation of the generator requirements if waste is kept on site beyond the accumulation time limits. The site

would be required to “close” the area where hazardous waste was accumulated as an illegal storage facility. If this is done, the **pharmacy** must be prepared to:

- Provide at least \$2 million of sudden accidental liability insurance
- Develop an engineered closure plan
- Decontaminate the area where waste was stored
- Pay fines/penalties

CESQGs: No time limit on accumulating and storing up to 1kg of acute hazardous waste or up to 1000 kg of non-acute hazardous waste

SQGs: Up to 1 kg of acute hazardous waste or more than 60000 kg may be kept on-site for 180 days (270 days if waste is to be shipped over 200 miles)

LQGs: Any quantity of hazardous waste on-site, but must ship ALL waste, acute and non-acute, off-site within 90 days of the date it was generated.

WHAT ARE THE REQUIREMENTS FOR CONTAINERS HOLDING HAZARDOUS WASTE?:

1) Conditionally Exempt Small Quantity Generators (CESQGs)

- No container requirements; containers should be in a good condition, be compatible, with the waste stored, kept closed except when adding or removing waste and be labeled.

2) Small & Large Quantity Generators (SQGs and LQGs):

- Containers must be in good condition, compatible with the waste they contain, be closed except when adding or removing waste, be labeled ‘Hazardous Waste’ with the date upon which the 90/180/270 day accumulation period begins.

FREQUENTLY ASKED QUESTIONS:

1) Do pharmacies need to dispose of hazardous waste if they are located in the front end of the pharmacy?

All waste generated at the **pharmacy** requires a waste determination. This includes waste generated in the actual **pharmacy** and other parts of the store. Common waste from other parts of the store may include nicotine patches and gum, drain cleaners, fingernail polish remover, alcohol containing beverages and products, lighters, batteries, household cleaners, fertilizers, pesticides and herbicides, just to name a few.

2) Can the take-back program be utilized?

No. Once a P-listed material is deemed unusable for its intended purpose, i.e., dispensed, it must be treated as a hazardous waste. In order for the material to be moved off site, the **pharmacy** is required to have that material be picked up by a registered hazardous waste transporter. Even as a conditionally exempt small quantity generator, the **pharmacy** will still be required to provide documentation that includes how the wastes were managed and disposed of, such as signed manifests, shipping papers or a bill of lading.

3) Where should pharmacies dispose of broken tablets?

A waste determination should be made to determine if the broken tablet is hazardous

or non-hazardous. This will determine if the waste can be disposed with the regular garbage or if it must be managed under the RCRA (hazardous waste) regulations.

4) Where should pharmacies dispose of vials from patients?

Vials from patients may be hazardous but are exempt from regulation under the household hazardous waste exemption.

5) Is there a difference in how P-listed drugs and U-listed drugs should be disposed of in the pharmacy?

No, both are hazardous waste. Both must be managed and disposed in accordance with the regulations.

6) Can P-listed drugs and U-listed drugs be combined together in the same hazardous waste container?

Facilities should not mix waste streams for a number of reasons some of which may result in violations or added expense for the facility.

7) Do CEQGs have to pay a fee for a transporter?

Hazardous waste transporters are commercial businesses and will charge a fee to transport a **pharmacy's** waste.

8) If the pharmacy (site) is required to "close" the area where hazardous waste was accumulated as an illegal storage facility, what area is included?

All areas of the facility where hazardous waste was stored are included. Closing a storage area as required by 40 CFR 264/265 Subpart G can be very expensive.

9) Can a CESQG dispose of hazardous waste in a contained (Subpart D) landfill?

CESQGs are required to dispose of their waste at a permitted facility. This included both Subpart C (hazardous waste) disposal facilities and at contained (Subpart D) landfills. The **pharmacy** should call the landfill prior to disposal to ensure the disposal company is permitted to accept hazardous waste from a CESQG. The call should be documented and kept on file for 3 years after the final shipment is made to the landfill.

The Division has ten regional offices across the state. Within these regional offices are Hazardous Waste Inspectors who conduct routine inspections on all hazardous waste generators. The inspector for your company can provide expert advice on hazardous waste management and will be glad to assist you.

A listing of the Division's Regional Offices follows.

Kentucky Division of Waste Management – Regional Offices		
Location	Address	Phone #
Bowling Green	2642 Russellville Road Bowling Green, Ky 42104	(270) 746-7475
Columbia	2751 Campbellsville Road Columbia, Ky 42728	(270) 384-4735
Florence	8020 Veterans Memorial Drive #110 Florence, Ky 41042	(859) 525-4923
Frankfort	200 Fair Oaks Lane Frankfort, Ky 40601	(502) 564-3358
Hazard	233 Birch St. Hazard, Ky 41701	(606) 435-6022
London	875 S. Main Street London, Ky 40741	(606) 330-2080
Louisville	9116 Leesgate Road Louisville, Ky 40222-4925	(502) 429-7120
Madisonville	Madisonville State Office 625 Hospital Dr. Madisonville, Ky 42431	(270) 824-7532
Morehead	525 Hecks Plaza Drive Morehead, Ky 40351	(606) 783-8655
Paducah	130 Eagle Nest Drive Paducah, Ky 42003	(270) 898-8468

Additional Resources:

Mr. Duke York
Internal Policy Analyst 3
State EPA
Department of Environmental Protection of the Division of Waste Management
200 Fair Oaks Lane
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(502) 564-6716
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Federal EPA link: <http://www.epa.gov/waste/hazard/generation/pharmaceuticals.htm>